

OCT 08 2008

K081884

E. 510(K) SUMMARY



MAJOR Prodotti Dentari S.p.A.
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SUBMITTER

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Document issued on	June 26, 2008

NAME OF DEVICE

Proprietary name	Major.base 20
Common name	Denture base material
Classification name	Denture relining, repairing, or rebasing resin (21 CFR 872.3760, Product Code EBI)
Predicate Devices	Paladon® 65 by Heraeus Kulzer GmbH & Co.K901789 Probase Hot by Ivoclar Vivadent AGK913655

DESCRIPTION OF THE DEVICE

Major.base 20 is a denture base, poly(methyl methacrylate)-based polymers for dental prosthesis. It can be used for:

- Total prosthesis
- Partial prosthesis
- Clasp dentures

Major.base 20 is a heat cure denture base material composed of a poly-methylmethacrylate polymer powder and a liquid consisting of methylmethacrylate and other ingredients solution.

Major.base 20 is substantially equivalent to predicate denture base system presently on the USA market and safety and effectiveness are well documented in the dental literature. All pigments used are approved for alimentary or similar use and are Cadmium free.

Polymerized material technical data (test performed by NIOM Laboratory – Norway) are the following:

- Flexural strength: 78 MPa
- Flexural modulus: 2390 MPa
- Water absorption: 22,0 $\mu\text{g}/\text{mm}^3$
- Water solubility: 1,5 $\mu\text{g}/\text{mm}^3$
- Residual monomer: 1,8 %

Major.base 20 is inherently safe when used according to the instructions for use. It is for use only by dental practitioners; it is not intended for OTC use.

TECHNOLOGICAL CHARACTERISTICS (compared to the predicate device)

Major.base 20 has the same technological characteristics as the predicate devices since all the devices are complying with ISO 1567:1999 or ADA/ANSI 12:2002 (Adoption of the ISO 1567:1999) and have:

- Same intended use
- Same polymers composition
- Same working technique

Finally our laboratory experience in using the listed devices is that you cannot find substantial differences: they are equivalent to major.base 20.

NONCLINICAL TESTING AND CONCLUSIONS

Taking in account that:

- the products and their formulation and use are widely described and totally accepted in dentistry (McKabe, J., Applied Dental Materials, 7th, Blackwell Scientif. Publ.; Phillips, J., Skinner's Science of Dental Materials, Saunders Co.; Graig and Oth., Dental Materials, Properties and Manipulation, 6th, Mosby Publ.; O' Brien, W. J., Dental Materials, Properties and Selection, Quintessence Books);
- a large amount of literature has assessed the clinical liability of these product types and their formulation, dedicating the attention to the denture base (see for instance articles registered on MedLine);

- these product types and their formulation are universal in the last fifty years manufacturing and clinical experience, counting for almost the totality of the denture bases in the world;
- the composition and philosophy of the evaluated products are exactly within what is described in most general literature;
- our company manufactures and sells these products, under similar formulations and processes, since 1966, without any record of human incompatibility or clinical evidence of adverse effects, having totaled, directly or through connected companies or transferred technologies, more than 150 tons of powders in the last ten years;

we can assess these statements:

- *the materials with which the products are manufactured, own a 50 years history of clinical research, testing and literature, which is largely sufficient not to request any further clinical research or testing;*
- *the products can then be considered clinically tested to be safe;*
- *the clinical monitoring is effected independently by the general literature and it is largely sufficient not to request any further research or testing.*



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Monica Funai
Quality and Regulatory Affairs
MAJOR Prodotti Dentari S.p.A.
Via Luigi Einaudi 23,
Moncalieri (Torino)
ITALY I-10024

Re: K081884

Trade/Device Name: Major.Base 20
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture, Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: September 10, 2008
Received: September 15, 2008

Dear Ms. Funai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

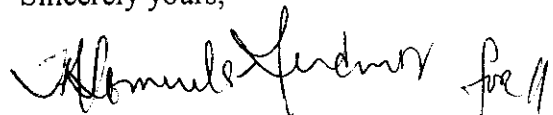
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu S. Lin", followed by a stylized flourish.

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081884



Indications for Use

510(k) Number (if known): _____

Device Name: **major.base 20**

Indications for Use: **Major.Base 20 is a denture base polymer for dental prosthesis. Poly-methylmethacrylate based. Heat-processed polymer. Powder and liquid.**

It is used for:

- dental prosthesis
- partial prosthesis
- clasp prosthesis

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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